UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CENTRAL STATES, SOUTHEAST AND SOUTHWEST AREAS, HEALTH AND WELFARE FUND, Plaintiff,	:	
v.	:	Civil Action No. 04-10817 WGY
SMITHKLINE BEECHAM CORPORATION and GLAXOSMITHKLINE, PLC, Defendants.	:	

ANSWER

Defendants Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") and GlaxoSmithKline PLC, by and through their undersigned counsel, hereby answer Plaintiff's Complaint as follows:

1. Defendants admit that plaintiffs have filed this lawsuit. Defendants further admit the second and third sentences of paragraph 1 and that until August 2001 no generic version of Relafen was marketed in the United States. The allegations of Paragraph 1 are otherwise denied.

2. Defendants admit that plaintiffs purport to bring the claims described in Paragraph 2. The allegations of Paragraph 2 are otherwise denied.

3. Defendants admit that plaintiffs purport to bring the claims described in Paragraph 3. The allegations of Paragraph 3 are otherwise denied.

4. Defendants admit that plaintiffs purport to bring the claims described in Paragraph 4. The allegations of Paragraph 4 are otherwise denied.

5. Defendants admit that plaintiffs purport to bring the claims described in Paragraph 5. The allegations of Paragraph 5 are otherwise denied.

6. GSK admits that venue is proper as to GSK. The allegations of Paragraph 6 are otherwise denied.

7. Denied.

8. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 8, and therefore deny those allegations.

9. Denied.

10. Admitted.

11. Defendants admit that GlaxoSmithKline PLC is a public company incorporated under the laws of England and Wales, with its principal headquarters there. Defendants further admit that GlaxoSmithKline PLC was formed following the December 2000 merger of SmithKline Beecham PLC and Glaxo Wellcome PLC. The allegations of Paragraph 11 are otherwise denied.

12. Defendants admit that Relafen is manufactured and sold by GSK, and was shipped across state lines and sold to customers located outside the state of manufacture.

Defendants further admit that GSK transmitted funds and communications pertaining to the sale of Relafen across state lines. The allegations of Paragraph 12 are otherwise denied.

13. Denied.

14. Defendants deny the first sentence of Paragraph 14. Defendants admit the second sentence of Paragraph 14. Defendants deny the third sentence of Paragraph 14 on the grounds that it uses terms that are inherently vague and ambiguous, such as "significant," "substantially," and "less severe." Defendants admit the fourth sentence of Paragraph 14.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 15, and therefore deny those allegations. Defendants also deny the allegations in Paragraph 15 because they are inherently vague and ambiguous.

16. Denied.

17. The document cited by plaintiffs speaks for itself. The allegations of Paragraph 17 are otherwise denied.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 18, and therefore deny those allegations.

19. The document cited by plaintiffs speaks for itself. The allegations of Paragraph 19 are otherwise denied on the grounds that it uses terms that are inherently vague and ambiguous, such as "significant."

20. Paragraph 20 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and related federal regulations and case law.

21. Paragraph 21 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

22. Defendants admit that the Approved Drug Products with Therapeutic Equivalence Evaluations is commonly called the Orange Book. The remainder of Paragraph 22 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

23. Paragraph 23 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

24. Denied.

25. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 25, and therefore deny those allegations. Defendants also state that Paragraph 25 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the applicable state laws regarding prescriptions and generic substitution.

26. Denied.

27. Paragraph 27 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

28. Paragraph 28 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

29. Paragraph 29 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

30. Paragraph 30 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

31. Paragraph 31 is a legal conclusion to which no answer is required. To the extent an answer is required, defendants refer the court to the text of the "FDCA," the "Hatch-Waxman Act," and related federal regulations and case law.

32. Defendants admit that they are the owners of the '639 patent, which contains claims to nabumetone. Defendants further admit that they have marketed Relafen®, whose active ingredient is nabumetone, in the United States since February 1992 pursuant to NDA No. 19-583. Defendants further admit that the term of the '639 patent was extended two years to expire on December 13, 2002. The allegations of Paragraph 32 are otherwise denied.

33. Defendants admit that Copley, Teva and Eon manufacture generic pharmaceutical products, that each of the Generic Manufacturers filed an ANDA and Paragraph IV certification alleging that the '639 patent was invalid, and that Teva acquired Copley on August 10, 1999. The allegations of Paragraph 33 are otherwise denied.

34. Defendants admit that the Generic Manufacturers gave written notice to SmithKline purporting to meet the requirements of 21 U.S.C. § 355(j)(2)(B)(i) and (ii). The allegations of Paragraph 34 are otherwise denied.

35. Defendants admit that they filed patent infringement suits within 45 days of receiving notice of each of the Paragraph IV certifications, and that the filing of these suits resulted in an automatic 30 month stay of approval pursuant to the FDCA and the Hatch-Waxman Act. Defendants further state that the provisions of the FDCA and the Hatch-Waxman

Act speak for themselves and thus no answer regarding those provisions is required. The remaining allegations of Paragraph 35, to the extent an answer is required, are denied.

36. Admitted.

37. Defendants state that the counterclaim suit speaks for itself and thus no answer is required. The remaining allegations of Paragraph 37, to the extent an answer is required, are admitted.

38. Admitted.

39. Admitted.

40. Admitted.

41. Defendants state that the defenses and counterclaims asserted by the Generic Manufacturers speak for themselves and thus no answer is required. The remaining allegations of Paragraph 41, to the extent an answer is required, are denied.

42. Denied.

43. Defendants state that the documents referred to in Paragraph 43 speak for themselves and thus no answer regarding their contents is required. To the extent an answer is required, defendants deny the allegations in Paragraph 43.

44. Defendants state that the document referred to in Paragraph 44 speaks for itself and thus no answer regarding its contents is required. To the extent an answer is required, defendants deny the allegations in Paragraph 44.

45. Defendants state that the document referred to in Paragraph 45 speaks for itself and thus no answer regarding its contents is required. To the extent an answer is required, defendants deny the allegations in Paragraph 45.

46. Defendants state that the document referred to in Paragraph 46 speaks for itself and thus no answer regarding its contents is required. To the extent an answer is required, defendants deny the allegations in Paragraph 46.

47. Defendants admit that the PTO issued the '639 patent on December 13, 1983. The allegations in Paragraph 47 are otherwise denied.

48. Defendants state that the document referred to in Paragraph 48 speaks for itself and thus no answer regarding its contents is required. To the extent an answer is required, defendants deny the allegations in Paragraph 48.

49. Denied.

50. Denied.

51. Denied.

52. Defendants admit that Eon received tentative approval of ANDA 75-280 on August 8, 1998. Defendants state that the effect of such tentative approval is governed by the

FDCA and the Hatch-Waxman Act, whose provisions speak for themselves and thus no answer regarding those provisions is required. Defendants further state that the letter referred to in Paragraph 52 speaks for itself and thus no answer regarding its contents is required. The remaining allegations of Paragraph 52, to the extent an answer is required, are denied.

53. Defendants admit that Teva received tentative approval of ANDA 75-189 on December 24, 1998. Defendants state that the effect of such tentative approval is governed by the FDCA and the Hatch-Waxman Act, whose provisions speak for themselves and thus no answer regarding those provisions is required. Defendants further state that the letter referred to in Paragraph 53 speaks for itself and thus no answer regarding its contents is required. The remaining allegations of Paragraph 53, to the extent an answer is required, are denied.

54. Defendants admit that the Infringement Actions extended beyond the expiration of the 30-month stay and that final approval for Teva's ANDA 75-189 was granted on May 26, 2000. The remaining allegation of Paragraph 54 are denied.

55. Admitted.

56. Paragraph 56 is a legal conclusion to which no answer is required. The court opinion cited by plaintiffs speaks for itself. To the extent an answer is required, defendants refer the court to the text of In re '639 Patent Litig., 154 F. Supp. 2d 157 (D. Mass. 2001).

57. Paragraph 57 is a legal conclusion to which no answer is required. The court opinion cited by plaintiffs speaks for itself. To the extent an answer is required, defendants refer the court to the text of In re '639 Patent Litig., 154 F. Supp. 2d 157 (D. Mass. 2001).

58. Paragraph 58 is a legal conclusion to which no answer is required. The court opinion cited by plaintiffs speaks for itself. To the extent an answer is required, defendants refer the court to the text of In re '639 Patent Litig., 154 F. Supp. 2d 157 (D. Mass. 2001).

59. Paragraph 59 is a legal conclusion to which no answer is required. The court opinion cited by plaintiffs speaks for itself. To the extent an answer is required, defendants refer the court to the text of In re '639 Patent Litig., 154 F. Supp. 2d 157 (D. Mass. 2001).

60. Paragraph 60 is a legal conclusion to which no answer is required. The court opinion cited by plaintiffs speaks for itself. To the extent an answer is required, defendants refer the court to the text of SmithKline Beecham Corp. v. Copley Pharm., Inc., 45 Fed. Appx. 915 (Fed. Cir. 2002).

61. Admitted.

62. Defendants admit that on October 31, 2002, defendants filed a Motion to Clarify the Disposition of the Appeal and Conform the Judgment. The allegations of Paragraph 62 are otherwise admitted.

63. Defendants admit that Teva commenced sales of generic 500 mg nabumetone in August 2001 and 750 mg nabumetone in September 2001.

64. Denied.

65. Denied.

66. Defendants incorporate by reference their answers to the preceding allegations.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Defendants admit that plaintiffs seek the relief identified in Paragraph 71. The allegations of Paragraph 71 are otherwise denied.

72. Defendants admit that plaintiffs seek the relief identified in Paragraph 72. The allegations of Paragraph 72 are otherwise denied.

73. Defendants incorporate by reference their answers to the preceding allegations.

74. Denied.

75. Denied.

76. Defendants admit that plaintiffs seek the relief identified in Paragraph 76. The allegations of Paragraph 76 are otherwise denied.

77. Defendants incorporate by reference their answers to the preceding allegations.

78. Denied.

79. Denied.

80. Defendants admit that plaintiffs seek the relief identified in Paragraph 80. The allegations of Paragraph 80 are otherwise denied.

81. Defendants incorporate by reference their answers to the preceding allegations.

82. Denied.

83. Denied.

84. Denied.

AFFIRMATIVE DEFENSES

1. The Complaint fails to state a claim upon which relief can be granted.

2. The Court lacks in personam jurisdiction over GlaxoSmithKline PLC.

3. Plaintiff's claims are barred, in whole or in part, by all applicable statutes of limitations and the doctrine of laches.

4. Plaintiff's claims are barred, in whole or in part, because plaintiffs and the members of the proposed class have not suffered antitrust injury to their business and property within the meaning of 15 U.S.C. § 15.

5. Plaintiff's claims are barred because they are not direct purchasers of Relafen.

6. At all times, defendants acted in good faith and in furtherance of their legitimate business interests and have caused no injury to competition, the public, or plaintiff.

7. Defendants' conduct is protected by the Noerr-Pennington doctrine and/or otherwise under the Constitution of the United States of America.

8. Defendants' conduct in submitting information on the subject patents to FDA for listing in the Orange Book was compelled by law.

9. Plaintiff's claims are preempted or precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the federal patent code, 35 U.S.C. § 101 *et seq.* (the "Patent Act").

10. Defendants' conduct was lawful under the Federal Food, Drug, and Cosmetic Act, the Hatch-Waxman Act, and the Patent Act.

11. Plaintiff's claims are barred by the Federal Food, Drug, and Cosmetic Act, the Hatch-Waxman Act, and the Patent Act.

12. Plaintiff lacks standing to assert claims under the laws of states other than the state in which it resides.

13. Plaintiff's claims are barred for failure to conform to notice and pleading requirements of the applicable state consumer protection statutes.

14. Plaintiff's claims are precluded because they do not meet the requirements for imposing liability for obtaining and enforcing a United States patent under the Walker Process and Noerr-Pennington doctrines.

WHEREFORE, defendants respectfully request that this Court enter judgment in their favor on plaintiffs' claims, dismiss plaintiffs' claims in their entirety, and award defendants costs, fees and such other relief as the Court deems just and appropriate.

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CERTIFICATE OF SERVICE
I hereby certify that a true copy of the above document was served upon the attorney of record for each other party by mail on 6-24-04

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